Remarks

This paper is submitted in response to the Final Office Action mailed on August 24, 2009. In this paper, new claims 65-69 have been added and claims 58-64 have been cancelled. Support for claim 65 can be found in the specification, for example, at page 35, lines 19-25. Support for claims 66-69 can be found in originally filed claims 3, 4, 5, and 15, respectively. No new matter has been added.

Claim Rejections - 35 U.S.C. §103

Claims 1, 3, 4, 6, 7, 8, 11, 20, 27, 58-61, 63 and 64 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al. (U.S. Pat No. 5,869,079) in view of Wong et al. (U.S. Pat No. 5,632,984; Wong '984).

Wong '079 relates to the use of solid slow release biodegradable implants. Wong '079 teaches that the release of the drug can be controlled by the rate of transport through the polymeric matrix of the implant and by the addition of a release modulator to the implant. The release modulator may act to accelerate or retard the rate of release. The implants of Wong '079 are of dimensions commensurate with the size and shape of the region selected as the site of implantation and will not migrate from the insertion site following implantation.

As admitted in the Office Action, Wong '079 does not specifically teach an injectable solution including the therapeutic medium. The Office Action supplements the deficiency in Wong '079 with Wong '984. The Office Action states that...

> *Wong '984 teaches intraocular administration of drugs that concentrate the drug at the site of the disease and where biodegradable microcapsules are employed, providing continuous, long-lasting treatment (see abstract and column 3, lines 8-9). Administration may be achieved by injection in a saline solution (see column 7, lines 63-65 and column 9, lines 63-67).*

The Office Action concludes that...

> *To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Wong et al. and suspending the microcapsules in a solution because Wong '938*

teaches that biodegradable microcapsules can be injected in a saline solution (see column 7, lines 63-65 and column 9, lines 63-67).

(note: Wong '938 above is understood as being Wong '984).

Wong '984 relates to the treatment of macular degeneration by the administration of drugs into the posterior segment of the eye in order to provide a therapeutically effective amount of the drug. Introduction into the posterior segment allows diffusion of the drug throughout the vitreous within the posterior segment and further into the entire retina, the choroids and opposed sclera. Of particular interest is the administration of interferon, particularly α-2a-interferon. In some embodiments the drug is delivered in biocompatible, biodegradable microcapsules in order to provide a slow release.

As noted above, the method of Wong '984 is practiced with a liquid that is injected into the posterior segment (i.e., vitreous) of the eye generally. The liquid is injected into the posterior segment where it is allowed to diffuse throughout the vitreous within the posterior segment and further into the entire retina, the choroid, and opposed schlera. The diffusion of the drug makes it available at the macula where the drug is needed (see, col. 4, lines 1-9). In Wong '984, the therapeutic medium is not localized at the choroid and the retina and minimized at other tissues of the eye as featured in Applicant's claimed methods. That is, in Wong '984 the drug diffuses throughout the entire vitreous in order to treat the desired portion of the eye. The Office Action states that Wong '984 is used as a reference to teach that therapeutic mediums such as those taught by Wong '079 can be administered via intraocular injection with a saline solution. However, in Wong '984, the microparticles are administered via a saline solution so that they can flow in the vitreous and so that a large number of particles can diffuse throughout the vitreous to the treatment site. Wong '984 does not teach that a liquid therapeutic medium can be directly injected sub-retinally at a desired treatment site in order to localize the action of the therapeutic medium at the choroid and the retina and minimize action at other tissues of the eye.

Wong '079 teaches the use of a solid implant to control the release rate of the therapeutic medium. There is no motivation to modify Wong '079 with Wong '984

because to do so would contradict the teachings of Wong '079 including the advantages taught of using a solid stationary implant in order to provide controlled release of the therapeutic medium.

In view of the foregoing, the rejection of the claims under 35 U.S.C. §103(a) as being unpatentable over Wong '079 in view of Wong '984 has been overcome and should be withdrawn.

Claims 5 and 62 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al. (U.S. Pat No. 5,869,079), in view of Wong et al. (U.S. Pat No. 5,632,984; Wong'984) as applied to claims 1-4, 6, 7, 8, 11, 20, 27, 58-61, 63 and 64 in view of Hughes et al. (U.S. Pat No. 5,962,027; "Hughes '027").

Claim 5 is a dependent claim that includes all of the limitations of the independent claim 1. Claim 1 is patentable for the reasons set forth herein. Therefore, claim 5 is also patentable for at least the same reasons as presented for independent claim 1. Claim 62 has been cancelled.

Claims 1, 8, and 11 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Louis (U.S. Patent No. 5,641,750) in view of Wong et al. (U.S. Patent. No. 5,869,079) and in further view of Hughes et al. (U.S. Patent No. 5,962,027).

Applicant respectfully traverses the rejection of claims 1, 8 and 11 under 35 U.S.C. §103(a).

Louis relates to a method for treating vision loss due to photoreceptor degeneration by administering a therapeutically effective amount of glial cell line-derived neurotrophic factor (GDNF) protein product. According to one aspect of the invention, methods are provided for treating vision loss due to photoreceptor degeneration by administering a therapeutically effective amount of GDNF protein product. It is contemplated that such GDNF protein products would include a GDNF protein such as that depicted by the amino acid sequence set forth in SEQ ID NO:1, as well as variants and derivatives thereof. It is reported that administration of GDNF protein product

promotes the survival and regeneration of damaged photoreceptor neurons, which are the main population of neurons damaged in retinal degenerations leading to blindness.

According to Louis, GDNF protein product may be administered intraocularly at a dose between about 0.001 mg/day and 10 mg/day, preferably at a dose between about 0.01 mg/day and 1 mg/day, and most preferably at a dose between about 0.1 mg/day and 0.5 mg/day. It is reported that the delivery means for the administration of a GDNF protein product in the treatment of ophthalmic conditions or diseases may involve topical formulations, ocular inserts, ocular injection, ocular implants, cell therapy or gene therapy.

As admitted in the Office Action, Louis does not teach administration to the posterior segment of the eye by directly instilling a solution therapeutic medium sub-retinally. The Office Action relies upon Wong '079 and Hughes to cure the deficiency in Louis. However, there is no motivation to modify the teachings of Louis using either Wong '079 or Hughes. Specifically, there is no reason to modify Louis because Louis specifically reports the suitable delivery methods, and there is no reasonable expectation of success that photoreceptor degeneration can be treated by GDNF protein using a sub-retinal instillation method. Additionally, both Wong '079 and Hughes relate to the implantation of solid implants or grafts into the eye. There is no motivation to modify Louis because one of skill in the art would not have a reasonable expectation of success that direct liquid instillation will take the place of, or be equivalent to, a solid implant or graft when sub-retinally implanted. The Office Action has combined Louis with Wong '079 or Hughes simply because these references relate generally to sub-retinal implantation. Here, the Examiner has attempted to assemble the elements of Applicant's claims from the prior art using Applicant's claims as roadmap, without motivation for making the proposed combination or reasonable expectation of success in making the proposed combination.

In view of the foregoing, the rejection of the claims under 35 U.S.C. §103(a) as being unpatentable over Louis in view of Wong '079 and further view of Hughes et al. has been overcome and should be withdrawn.

Conclusion

It is respectfully submitted that the claims and the present application are now in condition for allowance. Approval of the application and allowance of the claims is earnestly solicited. In the event that a phone conference between the Examiner and the undersigned would help resolve any remaining issues in the application, the Examiner is invited to contact undersigned at (651) 275-9830.

Respectfully Submitted,

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By: _____

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